Organic Materials Review Institute

November 8, 2005

Ms. Katherine Benham
USDA-AMS-TMD-NOP
1400 Independence Avenue, SW.
Room 4008–South Building, Ag Stop 0268
Washington, DC 20250–0200

Dear Ms. Benham:

OMRI appreciates the opportunity to comment to the NOSB on the sunset of materials. As I testified in August, OMRI does not support the retention or removal of any substance. OMRI appreciates and supports all of the NOSB recommendations for deferral proposed and offers to provide some limited technical assistance to the NOSB during the re-review process.

In addition to the substances proposed for deferral, the NOSB should also consider deferring nutrient vitamins (7 CFR 205.603d)(2)) and minerals (7 CFR 205.603d)(3) for both livestock production and synthetic nutrient vitamins and minerals in processing (7 CFR 205.605(b)).

In both cases, the recommendation from the NOSB was made without a TAP review of individual substances and a recommendation for accelerated re-review and sunset. The NOSB made that recommendation with respect to livestock (NOSB Recommendation 18, October 31, 1995) for re-evaluation in two years. The NOSB noted that in principle, organic animals are expected to receive most of their nutritional needs from organic sources, and synthetic sources should be decreased or eliminated. That re-evaluation never took place. With respect to the use in animal production, the reference to 'FDA approved' in the annotation has been subject to conflicting interpretations, as has been the need. Attached is a list of nutrient vitamins and minerals used in livestock production with OMRI's opinion regarding their NOP status.

Similarly, the NOSB called for re-review of nutrient supplementation of organic food (NOSB recommendation 13, October 31, 1995). The NOSB did not recommend the annotation referring to 21 CFR 104.20 in their initial recommendations. Instead, the NOSB recommended that the vitamins and minerals used in products labeled as organic be limited to those required by regulation or recommended for enrichment and fortification by independent professional associations. The NOSB should consider if the intent of the recommendation has been fulfilled and if the guidelines issued by FDA are appropriate.

Certain vitamins – such as ascorbic acid (vitamin C) and tocopherol (vitamin E) as well as nutrient minerals such as ferrous sulfate (iron) appear individually. Specific identification and recognition of legal requirements and case-by-case review where nutrients are not legally required may be more appropriate.

The NOSB should be aware growing number of vitamins are produced using genetically engineered organisms—excluded methods under 7 CFR 205.105(e)—making it ever more necessary to develop natural and from organically produced and non-synthetic sources. A TAP review needs to identify what nutrient vitamins and minerals are necessary, which ones are produced by excluded methods, and a substance by substance review similar to that required for amino acids.

PO Box 11558 • Eugene, OR 97440-3758 U.S.A.
Phone 541-343-7600 • Fax 541-343-8971
E-mail info@omri.org • www.omri.org

OMRI also asks that the NOSB defer the chlorine bleach products (7 CFR 205.605(b)). The annotation limits use to food contact surfaces and cleaning equipment. OMRI is aware of differing interpretations by certifiers. Greater clarity is needed about what is permitted in contact with food.

Please let us know if we can be of any further assistance.

Regards,

Brian Baker, Ph.D.
Research Director

Appendix C: Livestock Vitamins and Minerals

Listings for Livestock Nutrients by Source

This table represent OMRI's current policy for listing sources of livestock vitamins and minerals. OMRI policy is based on the NOP rule at 7 CFR 205.237(a), which allows the use of non-synthetic feed additives and supplements as well as those that are permitted by the National List. Section 205.603(d)(1-2) permits 'trace minerals / vitamins used for enrichment or fortification when FDA approved.' Forms of vitamins and minerals listed here include those regulated by FDA as listed in 21 CFR 582, (Subpart F, Nutrients and/or Dietary Supplements) and 21CFR 573, as well as those recognized in the AAFCO (Association of American Feed Control Officials) Official Publication under Section 57, Mineral Products, and Section 90, Vitamins.

OMRI considers that use of livestock vitamins and minerals is Restricted according to 7 CFR 205.237(b)(2), which states that "the producer of an organic operation must not . . . provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life."

Some sources of vitamins may be unacceptable either by interpretation of the NOP or under different standards. OMRI has identified forms that may be obtained from animal slaughter by-products, which are prohibited for feeding ruminants and poultry under 7 CFR 205.237(b)(5). Some sources of vitamins and minerals may contain synthetic nitrogen in the form of amino acids or ammonia, and such sources may be prohibited by private international or export organic standards. Some vitamin and mineral products may also contain products obtained from genetically modified organisms prohibited by the NOP Rule as 'excluded methods' at 7 CFR 205.105(e). Because of the development and commercialization of new products, changes in regulatory status, the table below may not be complete or up to date, and may be subject to further interpretation.

Appendix C: Livestock Vitamins and Minerals

OMRI status	Nutrient Activity / Source	AAFCO 2004 Reference	21 CFR
	Calcium		
P	Bone Ash *Animal slaughter by-products*	57.1	
P	Bone Charcoal *Animal slaughter by-products*	57.2	
P	Bone Charcoal – spent *Animal slaughter by-products*	57.17	
P	Bone Meal – cooked *Animal slaughter by-products*	57.141	
P	Bone Meal – steamed *Animal slaughter by-products*	57.18	
P	Bone Phosphate *Animal slaughter by-products*	57.14	
R	Calcite	57.3	
R	Calcium Carbonate	57.10	582.5191
R	Calcium Carbonate Precipitated	57.7	
R	Calcium Chloride	57.51	
R	Calcium Citrate		582.5195
P	Calcium Formate *Withdrawn from AAFCO. Calcium formate is currently considered an unapproved food additive.*	T57.152	
	Calcium		
R	Calcium Gluconate	57.52	
R	Calcium Glycerophosphate		582.5201
R	Calcium Hydroxide	57.53	
R	Calcium Iodate	57.54	582.80
R	Calcium Lactate		582.1207
R	Calcium Oxide	57.56	582.521
R	Calcium Periodate	57.25	
R	Calcium Phosphate	57.134	582.5217
R	Calcium Pyrophosphate		582.5223
R	Calcium Sulfate	57.57	582.523
R	Chalk – precipitated	57.8	
R	Chalk – rock	57.6	
R	Clam Shells – ground	57.131	
R	Dicalcium Phosphate	57.71	582.5217
R	Gypsiferous Shale	57.30	
R	Limestone – ground	57.9	

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	Calcium		
R	Limestone – Magnesium (Dolomitic)	57.11	
R	Monocalcium Phosphate	57.98	582.5217
R	Oyster Shell Flour	57.4	
R	Phosphate Rock – ground	57.20	
R	Phosphate Rock – ground, low fluorine	57.21	
R	Phosphate Rock – soft	57.15	
R	Shell Flour	57.5	
R	Tricalcium Phosphate	57.113	582.5217
	Chromium		
R	Chromium Tripiconlinate	57.155	
	AAFCO restricts to swine, at not more than 200 ppb in the diet.		
	Cobalt		
R	Cobalt Acetate	57.58	582.80
R	Cobalt Amino Acid Chelate	57.142	
R	Cobalt Amino Acid Complex	57.150	
R	Cobalt Carbonate	57.59	582.80
R	Cobalt Chloride	57.60	582.80
R	Cobalt Choline Citrate Complex	57.123	
R	Cobalt Glucoheptanate	57.148	
R	Cobalt Gluconate	57.147	
R	Cobalt Oxide	57.61	582.80
R	Cobalt Proteinate	57.23	
	Some non-organic protein may be derived from excluded methods (GMOs) or slaughter by-products.		
R	Cobalt Sulfate	57.62	582.80
	Copper		
R	Copper Acetate Monohydrate	57.153	
R	Copper Amino Acid Chelate	57.142	
R	Copper Carbonate	57.63	582.80
R	Copper Chloride	57.64	582.80
R	Copper Choline Citrate Complex	57.122	
R	Copper Citrate	57.158	
R	Copper Gluconate	57.65	582.526
R	Copper Hydroxide	57.66	582.80
R	Copper Lysine Complex	57.151	
R	Copper Orthophosphate	57.67	582.80
R	Copper Oxide	57.68	582.80
R	Copper Polysaccharide Complex	57.29	
R	Copper Proteinate	57.23	
	Some non-organic protein may be derived from excluded methods (GMOs) or slaughter by-products.		
R	Copper Pyrophosphate		582.80
R	Copper Sulfate	57.69	582.80
R	Cuprous Iodide	57.70	582.80
	Iodine		
R	3,5 Diiodosalicilic Acid	57.72	582.80
R	Calcium Iodate	57.54	582.80
R	Calcium Iodobehenate	57.55	582.80
R	Calcium Periodate	57.25	
R	Cuprous Iodide	57.70	582.80
R	Ethylenediamine Dihydriodide (EDDI)	57.75	582.80
	FDA does not permit use as an animal drug and limits amount fed to 50 g/head/day in dairy cattle. See Compliance Policy Guide 7125.18 from the FDA (http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg651-100.html)		

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	Iodine		
R	Iodized Salt	57.13	
	Depends on source of iodide		
R	Potassium Iodate	57.103	582.80
R	Potassium Iodide	57.104	582.80
R	Sodium Iodate	57.107	582.80
R	Sodium Iodide	57.108	582.80
R	Thymol Iodide	57.112	582.80
	Iron		
R	Ferric Ammonium Citrate	57.76	
R	Ferric Chloride	57.78	
R	Ferric Choline Citrate Complex	57.121	573.580
	FDA refers to 'iron-choline citrate complex.'		
R	Ferric Formate	57.127	
R	Ferric Phosphate	57.81	582.5301
R	Ferric Pyrophosphate	57.82	582.5304
R	Ferric Sodium Pyrophosphate		582.5306
R	Ferric Sulfate	57.129	
R	Ferrous Carbonate	57.77	
R	Ferrous Chloride	57.128	
R	Ferrous Fumarate	57.75	
R	Ferrous Glycine Complex	57.139	
R	Ferrous Lactate		582.5311
R	Ferrous Sulfate	57.83	582.5315
	205.605(b)		
R	Iron – reduced	57.84	582.80, 582.5375
R	Iron Amino Acid Chelate	57.142	
R	Iron Ammonium Citrate		582.80
R	Iron Carbonate		582.80
R	Iron Chloride		582.80

OMRI status	Nutrient Activity / Source	AAFCO 2004 Reference	21 CFR
	Iron		
R	Iron Gluconate	57.79	582.80
	Also known as 'Ferrous gluconate.'		
R	Iron Oxide	57.80	582.80
R	Iron Phosphate		582.80
R	Iron Polysaccharide Complex	57.29	
R	Iron Proteinate	57.23	
	Some non-organic protein may be derived from excluded methods (GMOs) or slaughter by-products.		
R	Iron Pyrophosphate		582.80
R	Iron Sulfate		582.80
	Magnesium		
R	Limestone – magnesium	57.11	
R	Magnesium Carbonate	57.85	582.1425
R	Magnesium Chloride	57.126	
R	Magnesium Hydroxide	57.86	582.1428
R	Magnesium Mica	57.24	
R	Magnesium Oxide	57.87	
R	Magnesium Phosphate	57.140	
R	Magnesium Proteinate	57.23	
	Some non-organic protein may be derived from excluded methods (GMOs) or slaughter by-products.		
R	Magnesium Sulfate	57.88	582.5443
	Manganese		
R	Manganese Acetate	57.89	582.80
R	Manganese Amino Acid Chelate	57.142	
R	Manganese Amino Acid Complex	57.150	
R	Manganese Chloride	57.91	582.5446
R	Manganese Citrate	57.92	582.5449
R	Manganese Gluconate	57.93	582.5452
R	Manganese Glycerophosphate		582.5455

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	Manganese		
R	Manganese Hypophosphite		582.5458
R	Manganese Methionine Complex	57.151	
R	Manganese Orthophosphate	57.94	582.80
R	Manganese Phosphate – dibasic	57.95	582.80
R	Manganese Proteinate	57.160	
	Some non-organic protein may be derived from excluded methods (GMOs) or slaughter by-products.		
R	Manganese Sulfate	57.96	582.5461
R	Manganous Oxide	57.97	582.80
	Phosphorous		
R	Ammonium Phosphate		582.1141
	AAFCO restricts use in ruminant feed, must supply no more than 2% of equivalent crude protein in total daily ration.		
R	Ammonium Polyphosphate Solution	57.22	
	AAFCO restricts use in ruminant feed, must supply no more than 2% of equivalent crude protein in total daily ration.		
P	Bone Meal – steamed	57.18	
	Slaughter by-products, prohibited		
R	Calcium Glycerophosphate		582.5201
R	Calcium Phosphate		582.1217
R	Calcium Pyrophosphate		582.5223
R	Diammonium Phosphate	57.16	573.320
	AAFCO restricts use in ruminant feed, must supply no more than 2% of equivalent crude protein in total daily ration.		
R	Dicalcium Phosphate	57.71	
R	Disodium Phosphate	57.32	582.1217
	Phosphorous		
R	Monoammonium Phosphate	57.33	582.1141
	AAFCO restricts use in ruminant feed, must supply no more than 2% of equivalent crude protein in total daily ration.		
R	Monocalcium Phosphate	57.98	582.1217
R	Monosodium Phosphate	57.99	
R	Phosphate – defluorinated	57.12	
R	Phosphoric Acid	57.19	
R	Potassium Glycerophosphate		582.5628
R	Rock Phosphate – ground	57.20	
R	Rock Phosphate – ground, low fluorine	57.21	
R	Rock Phosphate – soft	57.15	
R	Sodium Acid Pyrophosphate		582.1087
R	Sodium Aluminum Phosphate		582.1781
R	Sodium Hexametaphosphate	57.132	
R	Sodium Phosphate		582.5778
R	Sodium Tripolyphosphate	57.110	582.1810
R	Tricalcium Phosphate	57.113	582.1217
R	Trisodium Phosphate (Tribasic Sodium Phosphate	57.125	
	Potassium		
R	Potassium Bicarbonate	57.100	582.1613
P	Potassium Bisulfite	18.1	582.3616
	Chemical preservative, not a nutrient		
R	Potassium Carbonate	57.101	582.1619
R	Potassium Chloride	57.102	582.5622
	Non-synthetic 205.605(a)		

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OMRI status	Nutrient Activity / Source	AAFCO 2004 Reference	21 CFR
	Potassium		
R	Potassium Citrate *205.605(b)*	57.130	582.1625
R	Potassium Gluconate	57.162	
R	Potassium Glycerophosphate *R*		582.5628
R	Potassium Hydroxide *205.605(b)*	57.124	582.1631
P	Potassium Metabisulfite *Chemical preservative, not a nutrient*	18.1	582.3637
P	Potassium Sorbate *Chemical preservative, not a nutrient.*	18.1	582.3640
R	Potassium Sulfate	57.105	582.1643
	Selenium		
R	Sodium Selenate *FDA regulations limit use.*	57.120	573.920
R	Sodium Selenite *FDA regulations limit use.*	57.119	573.920
	Sodium		
R	Disodium Phosphate *205.605(b)*	57.32	
R	Monosodium Phosphate *205.605(b)*	57.99	
R	Salt (Sodium Chloride)	57.31	
R	Sodium Acetate		582.1721
R	Sodium Acid Pyrophosphate	57.137	582.1087
R	Sodium Aluminum Phosphate		582.1781
R	Sodium Bicarbonate	57.106	
R	Sodium Carbonate	57.133	
R	Sodium Caseinate		582.1748
R	Sodium Citrate		582.1751
R	Sodium Hexametaphosphate	57.132	
R	Sodium Hydroxide		582.1763
R	Sodium Iodate	57.107	582.80
R	Sodium Iodide	57.108	582.80
R	Sodium Pectinate		582.1775
R	Sodium Phosphate		582.5778
R	Sodium Sesquicarbonate	57.138	
R	Sodium Sulfate	57.109	582.80
R	Sodium Tripolyphosphate	57.110	582.1810
R	Trisodium Phosphate (Tribasic Sodium Phosphate)	57.125	
	Sulfur		
R	Calcium Sulfate	57.57	582.523
R	Cobalt Sulfate	57.62	582.80
R	Copper Sulfate	57.69	582.80
R	Ferrous Sulfate	57.83	582.5315
R	Iron Sulfate		582.80
R	Magnesium Sulfate	57.88	582.5443
R	Potassium Sulfate	57.105	582.1643
R	Sodium Sulfate	57.109	582.80
R	Sulfur – elemental	57.111	
P	Sulfuric Acid *General purpose, not a mineral nutrient in AAFCO.*		582.1095
R	Zinc Sulfate	57.118	582.80
	Zinc		
R	Zinc Acetate	57.114	582.80
R	Zinc Amino Acid Chelate	57.142	
R	Zinc Amino Acid Complex	57.150	
R	Zinc Carbonate	57.115	582.80
R	Zinc Chloride	57.116	582.80, 582.5985
R	Zinc Chlorine Diammine Complex	57.143	
R	Zinc Gluconate		582.5988
R	Zinc Lysine Complex	57.151	

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OMRI status	Nutrient Activity / Source	AAFCO 2004 Reference	21 CFR
	Zinc		
R	Zinc Methionine Complex	57.151	
R	Zinc Oxide	57.117	582.80, 582.5991
R	Zinc Polysaccharide Complex	57.29	
R	Zinc Proteinate	57.23	
	Some non-organic protein may be derived from excluded methods (GMOs) or slaughter by-products.		
R	Zinc Stearate		582.5994
	Some sources may come from slaughter by-products.		
R	Zinc Sulfate	57.118	582.5997
	Vitamin A		
R	Cod Liver Oil	90.1	
R	Cod Liver Oil with Added Vitamin A and D	90.2	
R	Vitamin A		582.5930
R	Vitamin A Acetate	90.25	582.5933
R	Vitamin A and D Oil	90.6	
	Some sources may come from slaughter by-products.		
R	Vitamin A Oil	90.3	
	Some sources may come from slaughter by-products.		
R	Vitamin A Palmitate	90.25	582.5936
R	Vitamin A Propionate	90.25	
R	Vitamin A Supplement	90.14	
	Vitamin B – complex		
R	Inositol	90.25	582.5370
	Vitamin B 1		
R	Thiamine	90.25	582.5875
R	Thiamine Hydrochloride	90.25	582.5875
R	Thiamine Mononitrate	90.25	582.5878

OMRI status	Nutrient Activity / Source	AAFCO 2004 Reference	21 CFR
	Vitamin B 2		
R	Riboflavin	90.25	582.5695
	AAFCO refers to 'crystalline riboflavin commercial feed grade.'		
R	Riboflavin Supplement	90.13	
R	Riboflavin-5-phosphate		582.5697
	Vitamin B 3 (Niacin)		
R	Niacin	90.25	582.5530
	Some sources may come from slaughter by-products.		
R	Niacin Supplement	90.16	
	Some sources may come from slaughter by-products.		
R	Niacinamide – nicotinamide	90.25	582.5535
R	Nicotinic Acid	90.25	582.5530
	Vitamin B 5 (Pantothenic acid)		
R	Calcium Pantothenate	90.25	582.5212
R	Sodium Pantothenate		582.5772
	Vitamin B 6		
R	Pyridoxine Hydrochloride	90.25	582.5676
	Vitamin B12		
R	Vitamin B12 Cyanocobalamin		582.5945
	Some sources may be produced by excluded methods (GMOs).		
R	Vitamin B12 Supplement	90.11	
	Some sources may be produced by excluded methods (GMOs).		
	Vitamin C		
R	Ascorbic Acid	90.25	582.5013
R	Calcium-L Ascorbyl-2-monophosphate	90.25	
	Stabilized ascorbic acid, feed grade AAFCO limits for use in fish feed only.		
R	Erythorbic Acid	90.25	582.3041
	Iso-ascorbic acid		
R	L-ascorbyl –2-polyphosphate	90.25	

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	Vitamin C		
R	L-ascorbyl-2-sulfate	90.25	
	AAFCO & FDA limit to aquatic species (Salmon, trout, catfish, shrimp, and tilapia).		
R	Magnesium L-ascorbyl-2 Phosphate	90.25	
	AAFCO & FDA limit to fish feeds only. Stabilized ascorbic acid.		
	Vitamin Choline		
R	Betaine	90.17	
	Hydrochloride or anhydrous. Some sources may come from slaughter by-products (stearyl betaine).		
R	Choline Bitartrate		582.5250
R	Choline Chloride	90.25	582.5252
R	Choline Pantothenate	90.25	
R	Choline Xanthate	90.25	573. 300
	Vitamin D		
R	Cod Liver Oil with Added Vitamin A and D	90.2	
R	Vitamin D2 (Calciferol)		582.5950
	Some sources may come from slaughter by-products.		
R	Vitamin D2 Supplement	90.4	
	Some sources may come from slaughter by-products.		
R	Vitamin D3 (Cholcalciferol)	90.7	582.5953
	D-activated animal sterol. Some sources may come from slaughter by-products.		
R	Vitamin D3 Supplement	90.15	
	Some sources may come from slaughter by-products.		
	Vitamin E		
R	a-Tocopherol Acetate	90.25	582.5892
R	Tocopherols	90.25	582.5890
	Vitamin H		
R	Biotin	90.25	582.5159

OMRI status	Nutrient Activity / Source	AAFCO 2004 Reference	21 CFR
	Vitamin K		
R	Menadione Dimethylpyrimidinol Bisulfite	90.25	573.620
	FDA and AAFCO limit rates: Chickens and turkeys, 2g/ton of feed; Swine: 10g/ton of feed. NRC does not recommend for ruminants. May come from slaughter by-products.		
R	Menadione Nicotinamide Bisulfite	90.25	573.625
	FDA and AAFCO limit rates: Chickens and turkeys, 2g/ton of feed; Swine: 10g/ton of feed. May come from slaughter by-products.		
R	Menadione Sodium Bisulfite Complex	90.25	
	AAFCO & FDA limit rate: Chickens and turkeys, 2g/ton of feed.		
	Vitamin M (Folic acid)		
R	Folic Acid – crystalline folic acid feed grade	90.25	